UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

March 10, 1998

OFFICE OF
THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

Note to the Reader:

The attached is a draft report of the Science Advisory Board (SAB). This draft is still undergoing final internal SAB review, however, in its present form, it represents the consensus position of the panel involved in the review. Once approved as final, the report will be transmitted to the EPA Administrator and will become available to the interested public as a final report.

This draft has been released for general information to members of the interested public and to EPA staff. This is consistent with the SAB policy of releasing draft materials only when the Committee involved is comfortable that the document is sufficiently complete to provide useful information to the reader. The reader should remember that this is an unapproved working draft and that the document should not be used to represent official EPA or SAB views or advice. Draft documents at this stage of the process often undergo significant revisions before the final version is approved and published.

The SAB is not soliciting comments on the advice contained herein. However, as a courtesy to the EPA Program Office which is the subject of the SAB review, we have asked them to respond to the issues listed below. Consistent with SAB policy on this matter, the SAB is not obligated to address any responses which it receives.

1. Has the Committee adequately responded to the questions posed in the Charge?
2. Are any statements or responses made in the draft unclear?
3. Are there any technical errors?

For further information or to respond to the questions above, please contact:

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EPA-SAB-RSAC-98-XXX - COMMITTEE REVIEW DRAFT #2
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Honorable Carol M. Browner
Administrator
U.S. Environmental Protection Agency
401 M. Street, SW
Washington, DC 20460

Subject: Review of the FY1999 Presidential Budget Request for the Office of Research and Development

Dear Ms. Browner:

On February 26-27, 1998, the Research Strategies Advisory Committee (RSAC) of the Science Advisory Board (SAB) met to review the FY1999 Presidential Budget Request for the Office of Research and Development (ORD) of the US Environmental Protection Agency (EPA). This review was carried out by RSAC in order to provide the Agency and the Congress with advice and insights on the adequacy of this budget to implement a research program of high scientific quality and one that is responsive to the needs of the Agency.

The review meeting was conducted in public session under the provisions of the Federal Advisory Committee Act (FACA). The Committee was provided with background documents supplied by the Agency, supplemented by briefings from Agency senior managers. The Committee was very pleased to see the significant improvement in the quality of the background materials as compared to previous years. In addition, we were impressed with the depth of knowledge exhibited and the level of coordination and cooperation displayed by the ORD senior staff members during the full day of presentations and briefings that helped us understand the FY1999 budget more clearly.

During the review meeting, the Committee considered how well the proposed budget request: a) reflected priorities identified in the EPA and ORD Strategic Plans; b) supported a reasonable balance in terms of attention to core research on multimedia capabilities and issues and to media-specific problem-driven topics; and c) balanced attention to near-term and to long-term research issues. In addition, the Committee offered its advice on: d) whether the objectives of the research and development program can be achieved at the resource levels requested; and e) how ORD can improve upon the Government Performance and Results Act (GPRA) structure to communicate research plans, priorities, research requirements, and planned outcomes.

The Committee reached the following conclusions:

a) The overall budget and its presentation were good. Presentations were clear and well-organized; the budget follows EPA and ORD Strategic Plans; and the budget is goal-based and incorporates the intent of GPRA.

b) The research budget is declining when viewed as percentage of the overall Agency budget.

c) Environmental concerns are complex and need more scientific insights than the budget can deliver, as a result, important issues may not be adequately addressed.

d) The Committee recommended that in future ORD requests that the budget should reflect not only the single year but the budget projected to meet each goal in the outyears.

e) The Committee has concerns that the Agency has not adequately demonstrated that this proposed ORD budget is sufficient, in a number of areas, to sustain the appropriate level of science and technology developments that the Agency needs to fulfill its mission to protect human health and to safeguard the natural environment.

f) It is important for EPA to develop an evaluation process so that they can better account for existing efforts (intramural and extramural) and to better assess needs for new research areas.

g) It would be useful for ORD to provide more detail on how the budget is allocated to individual objectives and research programs and how this year's budget fits in to the contemplated budgets over the planning horizon of the Strategic Plan.

We appreciate the opportunity to review and provide advice on the FY1999 Presidential Budget Request for the Office of Research and Development. The Research Strategies Advisory Committee would be pleased to expand on any of the findings in the attached report, and we look forward to your response.

Sincerely,

Dr. William Randall Seeker, Chair
Research Strategies Advisory Committee
Science Advisory Board

Dr. Joan M. Daisey, Chair
Executive Committee
Science Advisory Board

NOTICE

This report has been written as part of the activities of the Science Advisory Board, a public advisory group providing extramural scientific information and advice to the Administrator and other officials of the Environmental Protection Agency. The Board is structured to provide balanced, expert assessment of scientific matters related to problems facing the Agency. This report has not been reviewed for approval by the Agency and, hence, the contents of this report do not necessarily represent the views and policies of the Environmental Protection Agency, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names or commercial products constitute a recommendation for use.

ABSTRACT

On February 26-27, 1998, the Research Strategies Advisory Committee (RSAC) of the Science Advisory Board (SAB) met to review the FY1999 Presidential Budget Request for the Office of Research and Development (ORD). The Committee considered how well the proposed budget request: a) reflected priorities identified in the EPA and ORD Strategic Plans; b) supported a reasonable balance between core research on multimedia capabilities/issues and media-specific problem-driven topics; c) balanced near-term and long-term research issues; d) had sufficient resources to achieve the objectives of the research and development program; and e) how ORD can improve upon the Government Performance and Results Act (GPRA) structure to communicate research plans, priorities, research requirements, and planned outcomes.

The Committee noted that the FY1999 ORD and EPA budgets are the first goals-based research budgets put forth by the Agency. The budget represented a concerted effort on the part of the ORD to develop the requested funding allocations around the ORD Strategic Plan. The plan and budget were developed in concert with the program offices to develop goals consistent with customer needs. For the first time it is possible to examine and evaluate how the money is allocated to various programs, to science and technology activities and to various strategic goals.

Keywords: GPRA, budget, research, strategic planning

US ENVIRONMENTAL PROTECTION AGENCY
SCIENCE ADVISORY BOARD
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1. EXECUTIVE SUMMARY

On February 26-27, 1998, the Research Strategies Advisory Committee (RSAC) of the Science Advisory Board (SAB) reviewed the FY1999 Presidential Budget Request for the Office of Research and Development (ORD). The Committee was very pleased to see the significant improvement in the quality of the review materials as compared to previous years. In addition, we were impressed with the depth of knowledge exhibited and the level of coordination and cooperation displayed by ORD staff during the full day of presentations and briefings that helped the Committee members understand the FY1999 budget more clearly.

The Committee was tasked with considering how well the proposed budget request: a) reflected priorities identified in the EPA and ORD Strategic Plans; b) supported a reasonable balance in terms of core research on multimedia capabilities and issues and media-specific problem-driven topics; and c) balanced attention to near-term and to long-term research issues. In addition, the Committee was asked to offer advice on: d) whether the objectives of the research and development program can be achieved at the resource levels requested; and e) how ORD can improve upon the Government Performance and Results Act (GPRA) structure to communicate research plans, priorities, research requirements, and planned outcomes.

The Committee reached the following general conclusions:

a) The overall budget and its presentation were good. Briefings to RSAC were clear and well-organized; the budget follows EPA and ORD Strategic Plans; and the budget is goal-based and incorporates the intent of GPRA. The review process was important to obtain a better perspective over how the budget will be allocated through the entire course of the Strategic Plan instead of just a one year snapshot.

b) The budget is declining when viewed as a percentage of the overall Agency budget. The Committee found this a disturbing trend given the increasing complexity and cost of environmental problems.

c) Environmental concerns are complex and need more scientific insights than the budget can deliver, as a result, important issues may not be adequately addressed.

d) To fully meet stated goals, certain topics/goals need additional support. For example: pathogens in water and food; particulate matter research; endocrine disruption; and ecosystem protection. The Committee endorses the budget increases in the goals for empowering people and for global change. In addition, the Committee concurs with the priority given to clean air, safe water, and sound science goals

e) It is important for EPA to develop an evaluation process so that they can better account for existing efforts (intramural and extramural) and to better assess needs for new research areas.

f) It would be useful for ORD to provide more detail on how the budget is allocated to individual objectives and research programs and how this year's budget fits in to the contemplated budgets over the planning horizon of the Strategic Plan.

2. INTRODUCTION

2.1 Background and Schedule

The Science Advisory Board (SAB) review of the proposed budget for the Office of Research and Development is normally an annual event. The timing associated with the public availability of the budget materials often makes scheduling of a formal review difficult. Reviews completed by the Research Strategies Advisory Committee also require formal public review and approval of the SAB's Executive Committee. This year, the budget materials were released in early February, with the review materials made available to the Committee on or about February 18th. The Committee then met on February 26-27th, with a formal review and approval by the Executive Committee planned for March 31st.

Generally, the Chair or another Member of the Committee provides expert testimony to the House Committee on Science during its annual budget hearings, which are normally scheduled shortly after the release of the proposed budget. This year, the hearing is scheduled for March 11th.

2.2 Charge to the Committee

During the review meeting, the Committee considered how well the proposed budget request for FY1999: a) reflected priorities identified in the EPA and ORD Strategic Plans; b) supported a reasonable balance in terms of attention to core research on multimedia capabilities and issues and media-specific problem-driven topics; and c) balanced attention to near-term and long-term research issues. In addition, the Committee offered its advice on: d) whether the objectives of the research and development program can be achieved at the resource levels requested; and e) how ORD can improve upon the GPRA structure to communicate research plans, priorities, research requirements, and planned outcomes.

Responses to these questions, and others the Committee wishes to address, are provided to both the Agency and the Congress.

2.3 Format of this Report

Following the Executive Summary and this Introduction, this report contains two principal sections which cover the observations and conclusions of the Committee. Chapter 3 discusses the Committee's overall observations on the budget process and review, and offers some general comments. The specific responses to the questions in the Charge to the Committee are included in Chapter 4. In addition, Appendix A expands our observations regarding research on emerging issues.

3. OVERVIEW OBSERVATIONS AND COMMENTS

The Research Strategies Advisory Committee (RSAC) last formally reviewed the Office of Research and Development (ORD) budget for FY1995. At that review, the Committee had difficulty evaluating the adequacy and appropriateness of the budget plan due to the complexities in the accounting and reporting approach used by the Agency. The budget was not related to ORD goals but rather was aligned to a funding vehicle. The Committee recommended significant changes in the way that ORD planned research and reported the budget. In the current review, the RSAC noted substantial improvements in EPA-ORD planning and budgeting and it commends the Agency and the Office of Research and Development in making great strides. The process developed by EPA and ORD allowed a more functional presentation of the proposed budget and a rationalization of the decisions made in finalizing the funds for individual program elements.

Overall there is some concern regarding the adequate recognition and accounting for the key research and science and technology activities being conducted by EPA outside of EPA's ORD. There appear to be key activities ongoing in other parts of the Agency that are not captured in the science and technology budget numbers. A science and technology budget was developed which combined the ORD budget with Program Office laboratories. However, this does not account for the program office activities that are directed at regulatory development. The Committee is aware of the existence of "science for compliance" in program offices which also needs to be counted in a true measure of the Agency's science and technology budget.

The FY1999 ORD and EPA budgets are the first goals-based research budgets put forth by the Agency. The ORD budget represented a concerted effort to develop the requested funding allocations around the ORD Strategic Plan. The plan and budget were developed in concert with the program offices to develop goals consistent with customer needs. For the first time it is possible to examine and evaluate how the money is allocated to various programs, to science and technology activities and to various strategic goals. By presenting the requested fund allocations in the framework of the goals previously established in the ORD Strategic Plan, the Agency, and in turn, this committee could more clearly examine the relationship between the priorities articulated in the plan and the budget. In later sections, the Committee comments on its evaluation of the ORD and EPA requested science and technology allocations relative to each of the specific strategic goals. Regardless of the comments to be made on the specifics of the budget elements, the allocation mechanism was a clear improvement to the planning and review process. ORD has established a process that allows for more transparent accounting and can be built upon in the future for making allocation decisions in line with strategic goals and objectives. In later sections the Committee recommends some changes to the reporting process that will aid in future budget reviews as well as aid ORD's internal analysis of the budget.

The Committee notes the continued erosion of the ORD and Science and Technology budget relative to the overall EPA budget request. As shown in Figure 1, the ORD funding level has decreased dramatically in the last ten years as a fraction of the overall EPA budget. In the ORD funding requested for FY1999, the ORD budget is 6.6% of the entire EPA

requested budget. In 1995, the ORD budget was 12.6% of the EPA's budget and in 1989 the ORD budget was over 15% of the EPA budget. In addition, if the FY1999 ORD requested funds are allocated it will be the lowest in the 1990's when corrected for inflation. This erosion in ORD's and the Agency's science and technology funds occurs at the same time that the science involved with environmental issues is ever more complex and challenging. For example: a) the range of pollutants of interest to the Agency has been dramatically expanded with the passage of such significant legislation as the 1990 Clean Air Act Amendments, the 1996 Safe Drinking Water Act Amendments, and the 1996 Food Quality Protection Act; b) the need to address the levels of impacts of pollutants are known to occur at trace concentrations; c) ranges of mixture effects that have been recognized; d) the need to more completely address ecosystem impacts as well as susceptible human impacts; and e) the emerging environmental effects on which little is known such as endocrine disruptors and fine particulate matter. In the face of scientific uncertainty, and the need to control low levels of pollutants, EPA policy makers must make decisions balancing the potential for risk against the potential for substantial economic impacts from the decisions. Thus, decisions have to be made with potential for significant cost and benefit and must be done in the face of scientific uncertainties. It appears to the Committee to be inconsistent to have a proportionately and actually smaller science and technology budget in the face of the significance of the issues and the associated scientific uncertainty.

The Committee has concerns that the Agency has not adequately demonstrated that this proposed ORD budget is sufficient, in a number of areas, to sustain the appropriate level of science and technology developments that the Agency needs to fulfill its mission to protect human health and to safeguard the environment. It appears that the ORD has used their view of the realities of budget constraints to limit their vision of what research and science and technology activities they should be conducting. The ORD has developed its Strategic Plan and its goals and objectives within the bounds of the perceived budgetary constraints. The perception of the budget constraints appears to be driving the program planning and budget process and not the actual scientific needs. It is not clear to RSAC that the ORD and EPA have developed the vision of where they should be going to fully support the science mission of the Agency. The Agency needs to build on its strategic planning process to add an evaluation process which allows an assessment of problems that should be addressed that will support EPA's overall mission as well as support program office activities. It is important for EPA to develop this evaluation process so that they can better account for existing efforts (intramural and extramural) and to better assess needs for new research areas. In particular, the Committee concluded that goals may need to be expanded particularly with respect to identifying and addressing emerging environmental problems. In addition, the Committee concluded that the budgets proposed in several areas were not likely to be sufficient to meet the goals established by the Agency and ORD in their Strategic Plans. These areas included particulate matter, endocrine disruptors, ecosystem protection, global climate change, waste site remediation technologies, microbial pathogens and indoor air. The Committee frequently found it difficult to understand in detail how the budget for a major research goal would be distributed among the subsidiary objectives and individual research programs. For example, the Sound Science goal shows a budget of $50 million for the objective of anticipating future risks (termed "emerging risk issues" in this report), but the materials provided to the Committee do not show how it is allocated to the "One Atmosphere" program, endocrine disruptors, or the other components of this objective. This lack of detail makes evaluating the adequacy of the

budget difficult. In the future, ORD should provide sufficient detail for such evaluations.

The EPA and ORD must coordinate and draw upon the resources of other agencies and industry if it is to meet its overall mission of protecting human health and the environment. The SAB has often recommended that the Agency place a priority on the building of appropriate partnerships. The RSAC questions whether ORD has the capability to play a leadership role in the environmental protection field and develop a larger interagency and government-industry interaction. There is significant power in leveraging funds and coordinating activities with other organizations involved in environmental science and technology. In several cases (e.g., the STAR (Science to Achieve Results) program involving request for applications developed jointly and funded with other agencies, and the PM monitoring program) partnerships among EPA and other agencies and other private sector groups are being developed to leverage and coordinate funds better to meet ORD goals. These partnerships should be highlighted wherever possible in budget presentations to demonstrate EPA's initiative at seeking creative and cost-effective ways of meeting their objectives. It was not clear in the budget information provided to RSAC if the proper allocation of resources were being devoted to outside ORD coordination. The necessary resources include a travel budget that allows Agency scientists to communicate and coordinate more effectively with other groups as well as the allocation of researchers time to these important activities. In future budget presentations, RSAC recommends that ORD provide information that would allow an evaluation of the adequacy of the funding for coordination with organizations outside of EPA.

4. RESPONSE TO THE CHARGE

4.1 Reflecting Priorities in the Strategic Plans

<u>Charge Question</u>: Comment on how well the budget request reflects priorities identified in the EPA and ORD Strategic Plans

The RSAC completed its review of the FY1999 budget request recognizing the realities of the ORD budget history and the program directions. The Committee compliments the Agency for substantial improvements in the development and presentation of its budget in a goal-based format. As a result, we find that the budget is aligned with the EPA and ORD strategic priorities. The Agency has done a good job of justifying its budget requests on the basis of the research and development needs for each of the strategic goals. The goal-based budget presentation is very clear and easy to understand. The Committee observes that this budget has placed increased emphasis on empowering people and global change goals. This budget also places highest priority for clean air, clean and safe water, and sound science goals.

4.2 Balance Between Core Research and Problem Centered Research

<u>Charge Question</u>: Comment on how well the budget request supports a reasonable balance in terms of attention to core research on multimedia

capabilities and issues and to media-specific problem-driven topics.

It is appropriate that ORD should distribute its research resources to problem-program-regional and user needs as well as to continuing more fundamental core research themes. Core research activities can address multimedia issues, experimental designs, inter-agency cooperative activities, and emerging issues as well as issues that have extended-term significance to the Agency.

The National Research Council (NRC, 1997) has recently identified three important components of "core environmental research":

a) Investigation of the underlying processes that drive environmental systems,

b) development and demonstration of innovative research tools, including measurement techniques, models, and methods, and

c) collection and dissemination of accurate long-term environmental data.

Under ORD's current budget request, for example, the Ecosystems Protection and Human Health Risks objectives of the Sound Science Goal (core research) appear very consistent with the NRC's core environmental research needs.

The ORD indicated that in their FY1999 budget allocation, approximately 60 percent of resources are dedicated to core research and approximately 40 percent is devoted to problem research. This distribution was considered a reasonable relative distribution by the Committee. However, the Committee notes that there is no correct ratio or "balance" in a given year between budgetary allocations to these two activities beyond recognition of the need for both. For a specific budget year the resources distributed to problem and core research should be directed by the ORD Strategic Plan. This Plan, revised at minimum on a five-year cycle, should broadly define the relative allocations appropriate for its plan horizon and strive toward equal allocation to both themes over extended time.

It is also important for the Agency to build and maintain core competencies in critical environmental science and technology areas in order to be prepared for both foreseeable and unforeseeable environmental threats. Core competency includes both the facilities and the personnel expertise. The current budget report does not allow the RSAC or the Agency to examine the adequacy of the funding required to maintain the proper balance of core competencies in critical core areas. The Committee recommends that ORD undertake a review of the core competencies that it needs for the future to meet its long range mission. We believe that ORD should review both its current core competencies and its core competencies that will be substantially lost with the retirement of its aging personnel. The budget request should then reflect the resources needed to develop and maintain the required range and levels of core competencies.

4.3 Near-Term v. Long-Term Research

<u>Charge Question</u>: The Committee considered how well the proposed budget

request balances attention to near-term and to long-term research issues.

Most of the review materials focus on near term efforts. The core science program addresses longer term activities, in particular in the area of emerging issues. The new activities initiated to investigate the multiple pollutant impacts (One Atmosphere -- see section 4.4.7c)) program is a good example of longer term research that could provide a sound basis for future regulatory reform. There needs to be more effort placed on identifying longer term, proactive research agendas for EPA.

This charge focuses attention on a major problem in how we think about research issues. In general, there are research needs that are to be addressed in a research plan some of which can be accomplished in a limited time period and then ended. Other research needs may take five to ten years to provide significant new information, but which can potentially produce some useful results in the near-term as well as the long-term. Additionally, there may be some areas where there will not be short-term or intermediate results that contribute to near-term policy decisions. Finally, there are programs that should not be started until current research better defines the problem. Length of research programs should be defined in the Strategic Plan and represented in the annual budgets. Too often emphasis has been placed on programs which provide results in a time frame that is driven by regulatory schedules rather than their value to obtaining the critical understanding that is needed to proceed wisely with either more research or new regulations. Alternatively, it is better to think in terms of programs to be started now or started in the future and those that may or may not have intermediate results as the program progresses.

In terms of the balance between long and short duration programs, the Committee did not reach a conclusion concerning the current budget request because there is no indication of the potential duration of the programs nor an indication of what is anticipated as results become available. There is also no indication concerning how programs are evaluated for termination when they have fulfilled their objectives. For major programs, we recommend that the five-year time line provided in individual research plans be conveyed in the budget with an indication of anticipated funding levels and major milestones. Within the limits of our review, there are no programs that do not envision intermediate results and thus, certain types of research such as long term epidemiological studies are excluded. Such programs are likely to be important in certain areas and thus, it appears that there is undue emphasis on programs with short term results.

4.4 Objectives of Research v. Available Resources

<u>Charge Question</u>: The Committee considered whether the objectives of the research and development program could be achieved at the resource levels requested.

In the summary of the FY1999 budget, the EPA identifies the ten strategic, long-term goals from its Strategic Plan. These goals help to define the Agency's planning, budgeting, analysis, and accountability process. Seven of the ten goals apply to ORD and are discussed below: a) Clean Air; b) Clean and Safe Water; c) Preventing Pollution and Reducing Risk in Communities, Homes, Workplaces and Ecosystems; d) Better Waste Management,

Restoration of Contaminated Waste Sites, and Emergency Response; e) Reduction of Global and Cross Border Environmental Risks; f) Expansion of Americans' Right to Know about their Environment; and g) Sound Science, Improved Understanding of Environmental Risk, and Greater Innovation to Address Environmental Problems.

4.4.1 Strategic Goal: Clean Air

In this goal there is a major reduction in requested funding. Although the Committee understands the policy of not requesting continuation of earmarked funds that are directed to specific organizations, it appears that in the case of the additional funding for particulate matter (PM) research, the request to have the National Academy of Sciences prepare a 5-year research plan, and the results of the in-house research planning process including the workshop held in November 1997, the Agency has not shown that there will be the resources necessary for a research program that would produce a significant improvement of our understanding of the ambient PM health effects. To delay the implementation of the plan that will be delivered in the National Academy reports due in March and November 1998 until the FY2000 budget represents an undesirable delay in the study of what is described by EPA to be the most serious ambient air quality threat to public health and which will be extremely costly to implement. It could be reasonably anticipated that more than the base resources with a small increment will be needed in FY1999 to continue the program being initiated with the FY1998 PM funds that Congress has allocated for this purpose.

Part of the ORD air budget deals with the development of MODELS-3. The usefulness of this modeling tool depends on the adequacy of emissions inventories used by the modeling system. The extent to which other areas outside of ORD in EPA are addressing this concern should be noted.

Although the desire was to emphasize the implementation of the new PM and ozone (O_3) standards, it would make more sense to put the continuing costs of preparing criteria documents such as the one for carbon monoxide (CO) in this budget category rather than putting it under Emerging Issues. Since the law requires a regular cycle of criteria documents, it would make more sense to set aside a place for the continued funding of this review effort under the Clean Air Goal.

4.4.2 Strategic Goal: Clean and Safe Water

The clean/safe water research agenda focuses on the most specific immediate research needs for the development of pending regulatory decisions needed to comply with future implementation of the Safe Drinking Water Act. Other objectives are designed to provide information to better conserve and enhance the ecological health of the nation's waters and aquatic ecosystems. The objectives recognize the most critical needs and are highly focused, which should allow them to be achieved with the resources requested.

The Agency has made major efforts in adapting the risk paradigm to better focus their research agenda. Resources have been committed to develop and address critical needs in chemical and ecological risk assessment. The same commitment is needed to develop a microbial risk assessment paradigm that addresses multimedia exposure to pathogenic

microorganisms. This is critical to address emerging pathogens in our water and food supplies. Specific research monies are needed to develop this paradigm so that these threats can be better identified and research objectives and regulatory needs better focused. Current efforts are only designed to address drinking water regulatory needs in controlling microbial pathogens. This effort should be expanded to address issues recreational water quality, aerosol exposures, contaminated sediments, and pesticide efficacy. These microbial pathogen issues represents a research gap that has not been addressed by any agency.

4.4.3 Strategic Goal: Safe Communities

ORD proposes to devote $12 million to the goal of ensuring safe communities, homes, work places, and ecosystems. Of the research areas described in its Budget Plan, the substantial majority are categorized as increasing the use of safer or "greener" chemicals in commerce. However, the specific research topics are poorly related to that goal. While they may be valuable endeavors for achieving the overall goals of the Agency, it is difficult to evaluate the adequacy of the budget to achieve the stated goals. A much smaller budget ($2 million) is devoted to research on the human health risks of indoor air contaminants, which do seem relevant to the stated objective of increasing the indoor air quality for 15 million *more* Americans *than in 1994*. Although the budget request appears adequate to conduct the specific programs identified here, it is less certain that this budget is sufficient to address the overall problem of indoor air quality. On this same topic, it is possible that the balance between programs in indoor and ambient air is not optimal when their respective risk profiles are considered.

4.4.4 Strategic Goal: Safe Waste Management

The FY1999 budget request funds research under the Superfund Innovative Technology Evaluation (SITE), the Hazardous Waste Identification Rule (HWIR), Brownfields, and soil and groundwater remediation topics. It appears that the resources requested for this goal are adequate to achieve the results highlighted in the ORD Strategic Plan.

The Environmental Engineering Committee (EEC) of the Science Advisory Board (SAB) recently completed an in-depth review of the Waste Research Plan for EPA (SAB, 1998). The major findings of this review indicated that the overall planning process and the prioritization of research issues are appropriate and important. However, the waste research plan can be improved by capturing and documenting the decision process more completely and evolve to a position of flexibility in removing or adding research topics depending on the emerging needs. The SAB/EEC review also recommended that ORD establish linkages between the waste research strategy and parallel efforts within and outside the Agency.

4.4.5 Strategic Goal: Global Environmental Risk Reduction

The ORD global climate budget appears to be only a small part of the overall EPA global climate initiative budget. Given the current importance of global climate change and the

size of the overall Global Change Technology Initiative budget, it is important to better document how other areas within EPA are addressing critical research-related issues currently not covered within the ORD budget.

4.4.6 Strategic Goal: Environmental Right to Know

The RSAC endorses the emphasis on the EMPACT (the President's Environmental Monitoring for Public Access and Community Tracking) program, which is aimed at working directly with metropolitan areas to make information relevant and available to the public. Because the effort is expected to produce new processes for communication and data development and distribution, it is appropriately placed in ORD.

The Toxic Release Inventory (TRI) has been one of EPA's success stories. Using the TRI as a model for the EMPACT effort expands EPA's ability to empower people with information they need to make educated decisions and choices to protect their health. Information such as this also provides tools and guidance for those charged with protecting local, regional, and statewide public health. The RSAC concludes that the budget increment here is adequate to test the effectiveness of EMPACT.

4.4.7 Strategic Goal: Sound Science

This goal included four major objectives: ecosystem protection, human health risks, emerging risk issues and pollution prevention.

a) **Ecosystem Protection** - ORD's ecological resource research activities presently emphasize the Environmental Monitoring and Assessment Program (EMAP), development of stressor/response models, ecosystem assessment methods and ecosystem restoration technologies. In recognition of the value of these research themes, the importance of ecological resources to human societies, and the importance of EPA's need to distribute its activities on both human health and ecosystem health protection, RSAC was concerned to see a reduction in budget allocation in FY1999 relative to past fiscal years.

   The ORD Strategic Plan, the reorganized EMAP, and new STAR initiative all provide exciting research opportunities in the ecological resource area. The Committee is concerned about the reduction in the momentum of these efforts by imposing a budget reduction.

   Part of the reduction will be accompanied by establishing fewer "index sites" in National Parks under the new EMAP initiative. Reducing the number of index sites in National Parks is appropriate as many forms of research activities are excluded from National Park facilities. For nationwide representation, however, index sites need to be increased rather than reduced and they need to be located in facilities fully supportive of manipulative as well as descriptive research activities. Index sites should be expanded to include some long-term ecological research sites supported by the National Science Foundation (NSF).

b) **Human Health Risks** - Under this objective, ORD proposes to conduct research programs in multimedia/multipathway exposure models, mechanistic dose-response models, and susceptible populations. Although these program areas are quite broad, the budget request for $48 million seems adequate to make good progress during FY1999. The multimedia/multipathway residential exposure model is relevant to indoor air issues as well as (for example) household pesticides or consumer products. Mechanistic models for dose-response are sorely needed to replace default assumptions. While this effort will require ongoing attention over many years, the FY1999 budget should enable good progress on key environmental agents. ORD should continue its attention to investigating first those mechanisms and agents where uncertainties most limit decisions on the need for and severity of control measures.

c) **Emerging Risk Issues** - Within the objectives of emerging issues there are two components: "One Atmosphere" and "Endocrine Disruptors". The Committee commends the Agency for setting aside resources in order to explore emerging issues. However, at this time, there is no clearly defined process by which such issues are identified. Among other methods, the Exploratory Research Program could be helpful in identifying and initiating research in new areas that may emerge in the future. Thus, a focus on high risk, high reward research may provide a major payback. A consideration of this possibility may require an additional increment to provide the basis for truly exploratory projects.

1) <u>One Atmosphere</u> - The initiation of a program to examine the combined interactions of multiple species in the atmosphere is an important step forward. In the latest PM criteria document review, it was recognized that, although the strongest effects that could be extracted from the data were due to $PM_{2.5}$, there were statistically significant effects of other criteria pollutants. There are species that are important to both the formation of O_3 and $PM_{2.5}$. There are many other examples of where the broader examination of the atmosphere is essential to really define and resolve the issues. Thus, the start of a program examining the atmosphere in a holistic fashion is a valuable research initiative.

2) <u>Endocrine Disruptors</u> - The 1996 Safe Drinking Water Act Amendments and the 1996 Food Quality Protection Act require EPA to provide a set of screens and tests for compounds that could be found in drinking water or food that are estrogenic or may have other effects on the endocrine system. In light of these requirements, RSAC question<u>s</u> whether the FY1999 allocation for endocrine disruption is adequate. This directive could be interpreted as calling for testing a large number of the 72,000 industrial chemicals and 6,000 pesticide formulations in use. To date, there are no approved or validated screening methods or assays to thoroughly analyze the testing requirements of the Acts. In other words, no chemical to date has been adequately tested for its endocrine disruption effects. In essence, the policy is far ahead of the science in this case. For example, the Agency has until August 1998 to produce a set of screens and assays that will have passed peer review (by the Science Advisory Board or the Scientific Advisory Panel) for an interim trial program using 24

chemicals. This program must be implemented in fiscal year 1999, and by the year 2000, EPA must have evaluated the program and report back to Congress. The budget as presented does not provide enough specific information for the Committee to evaluate where current dollars are allocated or what is in the longer term research agenda to address endocrine disruption. Of the four areas under endocrine disruptors one is devoted to the topic of integrating field studies of human/wildlife populations. Further considerations on the relationships of human and animal endocrine disruption is provided in Appendix A.

d) **Pollution Prevention** - The focus and the related effort in Safe Wastes is not well articulated and the Committee had difficulty in fully understanding the differences in what was to be supported under these different goals.

4.5 Improvements to GPRA Structure

Charge Question: How can ORD improve upon the GPRA structure to communicate research plans, priorities, research requirements, and planned outcomes?

EPA should be commended on their development of a goal-based budget and planning process. The process is much easier to interpret and review and also provides a solid basis or identifying EPA program interconnections within EPA. RSAC strongly recommends that EPA now take the next important step in its strategic planning -- the development and implementation of an evaluation process for determining program effectiveness. The evaluation process will help justify budget decisions and help identify where changes are needed. It will also need to reflect the relationships between ORD and other Agency functions.

It would also be valuable to have an indication of how the present year fits into the flow of the research program funding by providing an indication of what the past year's funding was for each goal and the anticipated direction of funding (more, less, the same) for the next three years. Since most environmental problems are complex, it will take time to develop a real scientific basis for solutions. The continuity or lack thereof from year to year is an area that RSAC should comment on and thus, the Committee needs the data on which to base their review.

EPA needs to develop a set of criteria for success of research in ORD, whether it is done intramurally or extramurally. These criteria should include measures of the quality of the science (e.g., as indicated in peer reviewed journal papers) and the relevancy of the research to policy decisions that the Program Offices are required to make and the determination of the relative importance of emerging environmental issues and concerns. These criteria can then be incorporated into a process of reevaluation of research goals as they evolve over time to determine the continuing need for a particular research program and its potential value for informing the regulatory mission of the Agency.

In developing the criteria, we also recommend that the evaluation be results, not process, oriented. Criteria should focus on measures that relate to products that inform policy

makers. A full set of criteria for judging the value of both long term and short term problem-focused research need to be developed. Similarly, criteria for judging both required and anticipatory research need to be included.

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APPENDIX A

Integrating Field Studies of Human and Wildlife Populations

Clearly, the history of biology reveals the importance of focusing on less advanced animal species for several reasons in order to understand particular problems (e.g., health related). First, there is the need to translate what is known whether descriptive or experimental to humans. Second, primitive animal species, largely wildlife populations in the strictest sense are more nearly akin to humans, unlike their laboratory counterparts which are often inbred for many generations to yield genetically pure strains. Animals especially mice, are genetically engineered for a particular trait (knockout). In both instances, the animal model has been made simpler. This is however, not the case in wildlife populations nor humans neither of which are inbred nor genetically engineered. Third, wildlife populations and genetically simpler mice are both considered to be non-controversial - not so in the human population where certain moral/ethical questions often prevent the acquisition of emerging information or describe/predict the existence of potential hazards in the environment. Thus, if extrapolation and /or integration is to occur, there must be a component within the EPA goals which makes predictions, based upon field observations of what could develop in humans. Thus, a concerted effort by EPA to integrate field studies of human/wildlife populations is justified as a goal and requires serious consideration and a defined budget.

The environment now contains large quantities of several man-made chemicals which are potentially disruptive to the developing endocrine and nervous systems in wildlife and humans. During embryonic, fetal and early postnatal periods, these chemicals are especially damaging because they “resemble or interfere with the hormones, neuro-transmitters, growth factors, and other signaling that normally control development. These two systems are separate but also connected as the neuroendocrine system. Recent information now connects these two systems with the body's third regulatory system, the immune system. Linkages between the three are supported by data showing the sharing of various structural and regulatory components including cell surface markers and soluble molecules. Because of these connections forming the neuroendocrine immune complex, there is every reason to believe that these components are altered to the point of lesions or disease, covert/overt as a result of environmental toxicity. EPA can expect combined effects on the three conjoined regulatory systems as well as separately identifiable derangements in each system. The wildlife/humans connection may be defined in two ways: 1) observations showing similar effects in wildlife populations such as fish exposed to a xenobiotic and an effect produced in humans which have eaten fish; 2) connections that use wildlife populations as models from which extrapolations can be made to humans. With respect to endocrine disruptors there is little or no information on the environmental effects on invertebrates where there is substantial information on the neuroendocrine system. Moreover, there is information on the immune system and its experimental manipulation by xenobiotics. Because all animals share the earth as habitat this is the compelling reason for maintaining research that focuses on linkages between wildlife and humans.

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A REVIEW BY THE RESEARCH STRATEGIES ADVISORY COMMITTEE (RSAC) OF THE SCIENCE ADVISORY BOARD

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